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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,329	01/29/2004	Sean D. Monahan	Mirus.041.01	6227
25032	7590	11/16/2007	EXAMINER	
MIRUS CORPORATION			BARHAM, BETHANY P	
505 SOUTH ROSA RD				
MADISON, WI 53719			ART UNIT	PAPER NUMBER
			1615	
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			11/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/767,329	MONAHAN ET AL.
	Examiner Bethany P. Barham	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 02 October 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-8 and 21-24 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-8 and 21-24 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Summary*

#### **REQUEST FOR CONTINUED EXAMINATION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/2/2007 has been entered. Claims 1-8 and 21-24 are pending in this action. Claims 1-8 and 21-24 are rejected.

### **Response to Applicant**

Applicant argues that the previous RCE first action final rejection was improper, however see MPEP § 706.07(b), which states that a first action can be made final if no amendment to the claims is submitted and no new rejections of record are made. The previous first action final is **maintained**.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued

examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

The declaration under 37 CFR 1.132 filed 10/2/2007 is insufficient to overcome the rejection of claims 1-8 and 21-24 based upon the 35 U.S.C. 102(b) rejection of record by EP 0335133 A2 ('133) as evidenced by US 5,939,536 ('536) as set forth in the last Office action because: 1.32 declarations can not be used to overcome 102(b) rejection. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Due to Applicant's amendments and art submission the 35 U.S.C. 102(b) rejection of record by EP 0335133 A2 ('133) as evidenced by US 5,939,536 ('536) is hereby **withdrawn**.

## MAINTAINED REJECTIONS

### *Claim Rejections – 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,858,398 ('398) as evidenced by US 3,578,591 ('591).

'398 disclose pharmaceutical compositions comprising (1) phospholipids, (2) surfactants, (3) sterols, (4) pharmaceutically active agents, and (5) fatty acids having a chain length of C1 to C14 (Claim 1). According to '398, proteins, such as insulin, may be used as the active agent and surfactants, such as sorbitan monooleate, sorbitan sesquileate, and sorbitan monolaurate, may be used in the composition (Claims 1-2 and Example 1). As evidenced by '591, sorbitan monooleate, sorbitan sesquileate, and sorbitan monolaurate are all suitable detergents (column 6, lines 26-40). Like the instant claim set, the polypeptide complex advanced by '398 may be noncovalently bound and may be in "dry" form (column 12, lines 56; column 19, line 65 - column 20, line 5; and column 20, line 48). Sterol-based compounds are also added to the composition in order to increase the compositions "adherence to absorptive cells" (column 15, lines 35-54). '398 also set forth a process for making and using the above composition (Example 1, column 19, line 11 - column 20, line 52). According to '398, an insulin peptide may be combined with phospholipids, sterols, and surfactants (including the above detergents) and said complex may be dissolved in an organic solvent (Example 1). The polypeptide complex may then be dried (column 19, line 65- column 20, line 5 and Example 3). After preparing the polypeptide-complex, said complex can be dissolved in a suitable solvent and contacted with cells (column 26, lines 25 - column 27, line 60).

The claims are therefore anticipated by US 5,858,398 ('398) as evidenced by US 3,578,591 ('591).

## NEW REJECTIONS

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,858,398 ('398) in view of US 3,578,591 ('591).

'398 disclose pharmaceutical compositions comprising (1) phospholipids, (2) surfactants, (3) sterols, (4) pharmaceutically active agents, and (5) fatty acids having a chain length of C1 to C14 (Claim 1). According to '398, proteins, such as insulin, may be used as the active agent and surfactants, such as sorbitan monooleate, sorbitan sesquileate, and sorbitan monolaurate, may be used in the composition (Claims 1-2 and Example 1).

Like the instant claim set, the polypeptide complex advanced by '398 may be noncovalently bound and may be in "dry" form (column 12, lines 56; column 19, line 65 - column 20, line 5; and column 20, line 48). Sterol-based compounds are also added to the composition in order to increase the compositions "adherence to absorptive cells" (column 15, lines 35-54). '398 also set forth a process for making and using the above composition (Example 1, column 19, line 11 - column 20, line 52). According to '398, an insulin peptide may be combined with phospholipids, sterols, and surfactants (including the above detergents) and said complex may be dissolved in an organic solvent

(Example 1). The polypeptide complex may then be dried (column 19, line 65- column 20, line 5 and Example 3). After preparing the polypeptide-complex, said complex can be dissolved in a suitable solvent and contacted with cells (column 26, lines 25 - column 27, line 60).

'398 does not teach sorbitan monooleate, sorbitan sesquileate, and sorbitan monolaurate as detergents.

As is apparent by '591, sorbitan monooleate, sorbitan sesquileate, and sorbitan monolaurate are all known suitable detergents (column 6, lines 26-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made that '398 in view of '591 teaches a polypeptide-surfactant complex with detergents and also lipids. One of ordinary skill in the art would have been motivated to combine the teaching of '398 and '591, since '398 teaches the polypeptide-surfactant complex and including lipids to be contacted with cells and '591 teaches that the surfactants of '398 are known detergents. As such one would have a reasonable expectation of success in making the composition advanced by '398 including the known detergents of '591, also taught as surfactants '398.

### ***Response to Arguments***

Applicant's arguments filed 10/2/2007 have been fully considered but they are not persuasive. Applicants have argued that they are entitled to the generic limitation of dried noncovalently associated polypeptide/surfactant complexes wherein the surfactant consists of a detergent; the above rejections meet these limitations as they too are

directed to intracellular delivery of an identical complex to that as claimed in the instant application. The examiner respectfully submits that because the compositions are the same, the rejections stand.

Applicants argue that their invention is a composition consisting of a charged polypeptide and detergent of opposite charge, while '398 as evidenced by '591 teaches only a composition comprising a pharmaceutical agent, water soluble phospholipid, lipid soluble phospholipid, non-ionic detergent (HLB 15 or less), non-ionic detergent (HLB 6 or less) and water soluble sterol.

- The examiner respectfully points out that sterols are known lipids (instant claims 4 and 22).
- The pharmaceutical agent insulin is a protein (instant claims 1 and 21).
- The remaining ingredients, as shown above are phospholipids and surfactants or further detergents as claimed in the instant application (instant claims 1 and 21).

The instant claims are so generic that any polypeptide-surfactant complex can be made and '398 as evidenced by '591 makes a composition comprising only polypeptides and surfactants, and further a lipid which reads on the instant claim set (claims 1, 4, 21 and 22). Since '398 and '591 disclose the composition that contains only polypeptides, surfactants and lipids to be dissolved in an organic solvent and administered to cells absent a showing to the contrary by Applicant the compositions taught by the prior art are the same as instant claimed. As such the instant claims are either anticipated by '398 as evidenced by '591 or obvious over '398 in view '591.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany P. Barham whose telephone number is 571-272-6175. The examiner can normally be reached on M-F from 8:30am to 5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bethany Barham  
Examiner-1615

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